



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,495	07/16/2003	Robert F. Rioux	10123/00501	9066

7590 05/04/2006

Patrick J. Fay, Esq.
FAY KAPLUN & MARCIN, LLP
Suite 702
150 Broadway
New York, NY 10038

EXAMINER

AHMED, AAMER S

ART UNIT	PAPER NUMBER
----------	--------------

3763

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

JP

Office Action Summary	Application No.	Applicant(s)	
	10/620,495	RIOUX ET AL.	
	Examiner	Art Unit	
	Aamer S. Ahmed	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>07/16/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: reference element 22 in figure 1 is not mentioned in the description. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 12-17, 19, 20, 22-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler et al (US Patent Number 6,413,204 B1) in view of Houser (US Patent Number 6,632,196 B1). Winkler et al discloses a radioactive brachytherapy apparatus comprising an insertion member (10) having a distal end and a proximal end and a lumen extending between the proximal and distal ends, (see figure 4); and an inflatable member (34) deployable from the distal end of the insertion member, an inner chamber of the inflatable member being fluidly coupled to the lumen to receive an inflation fluid therefrom (see figure 4) so that when the inflation fluid is supplied to the inflatable member, the inflatable member expands to a substantially spherical shape (col. 3 line 57) ; and wherein the insertion member is a balloon catheter which is insertable through the insertion member in a deflated configuration and further comprising a luer (18) at the proximal end adapted to introduce inflation fluid to the inflatable portion via the lumen, a polymeric retention layer formed on the outer surface (col. 3 line 61) and wherein the apparatus expandable portion is sized to fill a lumpectomy cavity (col. 7 line 34).

Winkler et al ('204) fails to explicitly disclose that the insertion member have an outer diameter of approximately 5 FR. Examiner interprets the conversion of 1 FR to be equal to 1/3 mm. Accordingly, 5 FR is equal to 1.7 mm.

Houser discloses a similar apparatus in which the outer diameter of the insertion member is approximately 5 FR (col. 4 line 35).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Winkler et al ('204) by making the outside diameter of the balloon 5 FR as taught by Houser, in order to fit the desired diameter of the cavity.

Claims 8, 18, and 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler et al ('204) in view of Houser as applied to claim 1 above, and further in view of Winkler (US Patent Number 6,537,194).

Winkler et al ('204) and Houser disclose the apparatus above, but fail to disclose that the therapeutic agent is paclitaxel or that the balloon is adapted to receive a radioactive seed through the catheter.

Winkler ('194) discloses a similar device wherein the therapeutic agent is paclitaxel (see col. 6) and that the balloon is adapted to receive a radioactive seed through the catheter (col. 11 line 24).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Winkler et al ('204) in view of Houser, by adding the paclitaxel therapeutic agent and the balloon is adapted to receive a radioactive seed through the catheter as taught by Winkler ('194) in order to describe a common chemotherapeutic agent.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler et al ('204) in view of Houser as applied to claim 1 above, and further in view of Williams (U.S. Patent Number 6,083,148).

Winkler et al ('204) and Houser disclose the apparatus above, including an inner inflation chamber and an outer therapeutic chamber and wherein the inflation fluid chamber and the therapeutic chamber are sealed from one another (col. 4 line 4), but fails to disclose that the inflatable member comprises a plurality of perforations on the outer surface.

Williams discloses a similar device with perforations (col. 5 line 47).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Winkler et al ('204) in view of Houser, by adding the perforations of the type taught by Williams in order to better release the therapeutic agent to the site.

Response to Arguments

Applicant's arguments with respect to claims 1, 12, 2-3, 6-7, 10, 13-17 and 19-22 and 4-5, 23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3763

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



A. Ahmed



NICHOLAS D. LUCCHESI
SUPERVISOR, ART EXAMINER
TELEPHONE 571-272-4977

Application/Control Number: 10/620,495
Art Unit: 3763

Page 7